K083729

BIOMET®
MANUFACTURING CORP.

510(k) Summary

APR - 3 2009

Preparation Date: November 26, 2008

Applicant/Sponsor:
Biomet Manufacturing Corp.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587
Establishment Registration Number: 1825034

Contact Person:
Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name: MAK OSS Knee Femoral Components

Common Name: Total Knee Replacement

Classification Name: Knee joint femoraltibial metal/polymer constrained cemented prosthesis (21 CFR 888.3510)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

K002757	Oncology Salvage System
K051479	RS (Reduced Size) OSS (Orthopedic Salvage System) Component
K052685	Orthopedic Salvage System – OSS

Device Description:
There are two styles of MAK OSS Knee Femoral components, resurfacing and segmental. They have a plasma spray porous coating on the distal bone/implant interface surface and the articular surfaces have a color buff surface and two holes in the posterior condyles accommodate the femoral bushings and axle that connect the femoral component to the tibial component to create a hinged knee.

A polyethylene hyperextension bumper component fits into a pocket between the femoral condyles at the time of surgery. The bumper limits the amount of extension allowed by the implant.

Mailing Address:
P.O. Box 587
Warsaw, IN 46581-0587
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Office: 574.267.6639
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www.biomet.com

Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

Intended Use:
Biomet's OSS Knee System is intended for use in total knee replacement. Specific indications for these devices are:

1. Painful and disabled joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis or traumatic arthritis.
2. Correction of varus, valgus or post traumatic deformity
3. Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement.
4. Ligament deficiencies
5. Tumor resections
6. Treatment of non-unions, femoral neck and trochanteric fracture of the proximal femur with head involvement, unmanageable using other techniques
7. Revision of previously failed total joint arthroplasty
8. Trauma

These devices are to be used with bone cement

Summary of Technologies:
The MAK OSS Knee Femoral Components have the same technological characteristics as the predicates listed above.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 3 2009

Biomet Manufacturing Corp.
% Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
56 East Bell Drive, P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K083779
Trade/Device Name: MAK OSS Knee Femoral Components
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: II
Product Code: KRO
Dated: December 17, 2008
Received: January 5, 2009

Dear Ms. Beres:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083779

Device Name: MAK OSS Knee Femoral Components

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Prescription Use X AND/OR Over-The-Counter Use NO
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083779